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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,928	10/05/98	INOMATA	N 001560-336

021839 HM22/0426  
BURNS DOANE SWECKER & MATHIS  
P O BOX 1404  
ALEXANDRIA VA 22313-1404

EXAMINER  
BORIN, M

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 04/26/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No. 528  
09/171,238

Applicant(s)

Inomata et al.

Examiner

M. Borin

Group Art Unit

1631



☒ Responsive to communication(s) filed on Feb 9, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) 1-5 and 15-20 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 6-14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Status of Claims***

1. Response to restriction requirement filed 02/09/00 is acknowledged. Applicant elected, with traverse, Group II, claims 6-14. Applicant argues that Groups I and II should be rejoined as drawn to product and method of its use. As was explained in the restriction requirement, Group I, which is the technical feature that links Groups I to III, is not the contribution over the prior art because it is suggested by multiple references teaching pharmaceutical compositions of agents effecting natriuretic peptide receptor. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2. The intended use recited in the claim language drawn to pharmaceutical composition does not impart patentability of the claim. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1-5, 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected groups.

### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statement filed 05/10/98 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

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***Drawings***

3. The drawings are accepted.

***Claim Rejections - 35 U.S.C. § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites "the natriuretic peptide receptor". It is not clear which particular receptor out of plurality of natriuretic receptors, is meant.

***Claim Rejections - 35 U.S.C. § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-10 is rejected under 35 U.S.C. 102(b) as clearly anticipated by Blaine et al. (US Patent 4652549) as evidenced by Espiner<sup>1</sup>.

Blaine teaches method of treatment of cardiac hypertrophy using atrial natriuretic peptide (ANF) and fragments thereof. See abstract, summary, claims 1-8. The referenced method anticipates the instantly claimed method of treatment of heart disease based on hypertrophy comprising administration of a substance that acts on natriuretic receptor, guanylyl cyclase A and is able to accelerate production of cGMP. Note, that it is well known that ANF, as well as its analogs stimulate guanylate cyclase A and production of cGMP. See Espiner, p. 205, last paragraph. Therefore, the effects of ANF as instantly claimed are inherently present.

In regard to claim 7, chronic heart failure is a disease based on cardiac hypertrophy.

In regard to claim 10, Espiner teaches that BNP is a functional equivalent of ANP. See p. 205, right column through p. 206, left column.

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<sup>1</sup>Note that, although the date of the "Espiner" reference is later than the priority date of the instant application, the reference is a review describing studies preceeding the instant application; the reference is used merely to demonstrate well known mechanisms of action.

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6. Claims 6-10 is rejected under 35 U.S.C. 102(b) as clearly anticipated by Neustadt et al. (US Patent 5356925).

Neustadt et al. teach treatment of cardiovascular disorders, such as hypertension, congestive heart failure, renal insufficiency (i.e. diseases based on cardiac hypertrophy) using combination of natriuretic peptide(s) and ACE inhibitor. The referenced method anticipates the instantly claimed method of treatment of heart disease based on hypertrophy comprising administration of a substance that acts on natriuretic receptor, guanylyl cyclase A and is able to accelerate production of cGMP. Note that the claimed language “comprising” is not limited on one active ingredient and thus reads on methods of use of formulations comprising natriuretic peptide. Further note, that it is well known that ANF, as well as its analogs stimulate guanylate cyclase A and production of cGMP. See Espiner, p. 205, last paragraph. Therefore, the effects of ANF as instantly claimed are inherently present.

In regard to claim 10, Espiner teaches that BNP is a functional equivalent of ANP. See p. 205, right column through p. 206, left column.

7. Claims 6-9 are rejected under 35 U.S.C. 102(b) as clearly anticipated by Berman et al. (JP 63303998) as evidenced by Espiner<sup>2</sup>.

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<sup>2</sup>Note that, although the date of the “Espiner” reference is later than the priority date of the instant application, the reference is a review describing studies preceeding the instant application; the reference is used merely to demonstrate well known mechanisms of action.

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Berman et al. teach treatment of cardiac hypertrophy using atrial natriuretic peptide (ANF) analogues which bind to natriuretic receptor. See abstract. The referenced method anticipates the instantly claimed method of treatment of heart disease based on hypertrophy comprising administration of a substance that acts on natriuretic receptor, guanylyl cyclase A and is able to accelerate production of cGMP. Note, that it is well known that ANF, as well as its analogs stimulate guanylate cyclase A and production of cGMP. See Espiner, p. 205, last paragraph. Therefore, the effects of ANF analogues as instantly claimed are inherently present.

8. Claims 6,11-14 are rejected under 35 U.S.C. 103(a) as obvious over Blaine or Berman or Neustadt. The references are applied as above.

If there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal ways of administration and pharmaceutical carriers as they are art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

***Conclusion.***

8. No claims are allowed

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 17, 2000

mlb



**MICHAEL BORIN, Ph.D.**  
**PATENT EXAMINER**